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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 101713-01-5033-US

VIA ELECTRONIC FILING

on October 20, 2011

Signature /Thomas M. Sossong, Jr./

Typed or printed name Thomas M. Sossong, Jr.

Application Number	Filed
10/560,544	December 14, 2005

First Named Inventor: Breda Mary Cullen et al.

Art Unit	Examiner
1618	Nissa M. Westerberg

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 48,463.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Thomas M. Sossong, Jr./
Signature

/Thomas M. Sossong, Jr./
Typed or printed name

215.963.5809
Telephone number

October 20, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

VIA ELECTRONIC FILING **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent Application of Breda Mary Cullen *et al.*	: :	Attorney Docket No.: **101713-5033**
Appln. No.:	**10/560,544**	:	Examiner: Nissa M. Westerberg
Filed:	December 14, 2005	:	Confirmation No.: 6443
For:	ANTIOXIDANT WOUND DRESSING MATERIALS	: Group Art Unit: 1618	

NOTICE OF APPEAL AND
PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This Pre-Appeal Brief Request for Review and accompanying Notice of Appeal pursuant to 37 C.F.R. § 41.31 are submitted in response to the Office Action mailed May 20, 2011, and Applicants respectfully request the remarks herein be made of record and considered in the above-identified patent application prior to the filing of an appeal brief. This response is timely filed in view of the Petition for Two Month Extension of Time and accompanying fee filed herewith, which extends the time for response up to and including October 20, 2011.

Listing of Claims

1. (Previously presented) A wound dressing material comprising a solid bioabsorbable substrate dyed with an antioxidant dyestuff, wherein the solid bioabsorbable substrate comprises oxidized cellulose and is selected from the group consisting of woven fabrics, nonwoven fabrics, freeze-dried sponges, solvent-dried sponges and combinations thereof, wherein the antioxidant dyestuff is an antimicrobial, and wherein the antioxidant dyestuff is bound to the surface of the solid bioabsorbable substrate and allows sustained release of antioxidant effective amounts of the antioxidant dyestuff.

2.-4. (Canceled)

5. (Previously presented) A wound dressing material according to claim 1, wherein the antioxidant dyestuff is selected from the group consisting of aniline dyes, acridine dyes, thionine dyes, bis-naphthalene dyes, thiazine dyes, azo dyes, anthraquinones, and mixtures thereof.

6. (Previously presented) A wound dressing material according to claim 1, wherein the antioxidant dyestuff is selected from the group consisting of gentian violet, aniline blue, methylene blue, crystal violet, acriflavine, 9-aminoacridine, acridine yellow, acridine orange, proflavin, quinacrine, brilliant green, trypan blue, trypan red, malachite green, azacrine, methyl violet, methyl orange, methyl yellow, ethyl violet, acid orange, acid yellow, acid blue, acid red, thioflavin, alphazurine, indigo blue, methylene green, and mixtures thereof.

7. (Previously presented) A wound dressing material according to claim 6, wherein the antioxidant dyestuff is present in an amount of from about 0.2 to about 2 wt.% based on the dry weight of the material.

8. (Previously presented) A wound dressing material according to claim 7, wherein the material further comprises a silver salt, whereby the dyestuff photostabilizes the silver salt.

9. (Original) A wound dressing according to claim 8, wherein the polymeric substrate comprises an anionic polymer, and said silver salt comprises a salt of Ag+ with the anionic polymer.

10. (Previously presented) A wound dressing material according to claim 9, wherein the composition comprises from about 0.01 wt.% to about 5 wt.% of silver, based on the dry weight of the composition.

11. (Previously presented) A wound dressing material according to claim 7, wherein the material is in sheet form.

12. (Previously presented) A wound dressing material according to claim 7, wherein the material is sterile and packaged in a microorganism-impermeable container.

13. (Previously presented) A wound dressing material according to claim 7, wherein the material has a free radical activity in the diphenylpicrylhydrazyl (DPPH) test for antioxidant activity of at least 15%.

14–19. (Canceled)

20. (Previously presented) A wound dressing material according to claim 1, wherein the oxidized cellulose is an oxidized regenerated cellulose.

REMARKS

Applicants respectfully request consideration of the following comments.

Rejections under 35 U.S.C. § 103(a)

All of claims 1, 5-13 and 20 are variously rejected on several bases as allegedly obvious in view of a combination of various prior art references (*See* 05-OCT-2010 Office Action, items 5-8). Applicants respectfully traverse the Examiner's rejections on the grounds that a *prima facie* case of obviousness, in addition to the reasons set forth in the response filed April 5, 2011.

Each outstanding obviousness rejection alleges obviousness in view of at least Partain et al. (EP0368253) and Britton et al. (US 2003/0007957). In part, each rejection is based on the bald assertion that Britton teaches that chitosan and oxidized regenerated cellulose (ORC) are functionally equivalent (*See*, e.g., bottom of page 7, 05-OCT-2010 Office Action). This allegation is overly broad and not supported by any facts, and no basis is given for the motivation of the skilled artisan to conclude that the disclosure of Britton can or would be combined with the disclosure of Partain. Further, no basis is given for the motivation of the skilled artisan to conclude that a combination of Britton and Partain with any of the other cited references can or would lead the skilled artisan to the presently-pending claims. Therefore, the rejections do not meet the burden required to establish a *prima facie* case of obviousness.

Britton teaches – at most – that chitosan and ORC are equivalent for the specific and narrow purpose of the invention taught by Britton. Specifically, paragraph [0022] of Britton states that the "[C]ommon feature of the above-described group of substrates is the ability to create a gelatinous consistency ranging from semi-liquid to semi-solid when mixed with unactivated platelet-rich plasma." (Emphasis added). In fact, every embodiment of the invention disclosed by Britton requires the use of platelet-rich plasma obtained from the patient to be treated. This teaching provides no suggestion or motivation to functionally equate chitosan with ORC for any other purpose whatsoever. To do so is even in contradiction to Partain, as discussed below. Beyond this, Britton does not mention, suggest, or refer to chitosan or ORC in any capacity. No reason is provided in the Office Action as to why the skilled artisan would consider the two substances equivalent in view of Britton.

As admitted in the Office Action, Partain does not teach or suggest ORC in any manner (*See* bottom of page 7, 05-OCT-2010 Office Action). Furthermore, a reading of Partain, for all it fairly teaches, reveals that Partain focuses on the utility of chitosan aminopolysaccharides to the exclusion of other substances. Lines 42-53 in column 2 of Partain illustrate that all embodiments of the invention require from 0.01-99.99 weight percent of a chitosan substance. Further still, column 3, lines 20 – 35 of Partain, illustrates that in acidic conditions, chitosan is protonated and is thus able to bind to negatively charged surfaces such as mucosal membranes. Such a property is very different from ORC, which will only form an anionic moiety, and therefore, not be expected to have the same binding properties. Therefore, the teachings of Partain provide no suggestion or motivation to functionally equate chitosan with ORC for any purpose whatsoever. No reason is provided in the Office Action as to why the skilled artisan would consider the two substances equivalent in view of Partain, or how Partain could be combined with Britton to come to the conclusion that the two substances are equivalent.

None of the remaining references - Cullen, Shanbrom, Nimrod, or Gibbins - cures the deficiencies of Partain and Britton. None of Cullen, Shanbrom, Nimrod, or Gibbins provides any teaching or suggestion as to how or why the skilled artisan would equate ORC and chitosan, two physically and chemically different substances. None of Cullen, Shanbrom, Nimrod, or Gibbins provides any teaching or suggestion as to how or why the skilled artisan would combine Partain and Britton for the purpose of equating chitosan and ORC. Most significantly, the Office Action does not provide any factual basis as to why the skilled artisan would combine Partain with Britton, then combine the two with any of the remaining cited references, nor does the Office Action provide the basis for any motivation required by the skilled artisan to combine any of the references, on the foundation of Partain and Britton, in order to reach the conclusion that chitosan and ORC are physically, chemically or biologically equivalent, much less equivalent for the purpose of arriving at Applicants' presently-pending claims. Therefore, none of the rejections meets the burden required to establish a *prima facie* case of obviousness.

Accordingly, none of the references, as combined in the Office Action, provides any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious, as set forth above, Applicants respectfully request withdrawal of the rejections of claims 1, 5-13 and 20 under 35 U.S.C. § 103(a).

Double Patenting Rejection

The double-patenting rejection is based on the teachings of Partain. As admitted in the Office Action, Partain does not teach or suggest ORC in any manner (*See* bottom of page 7, 05-OCT-2010 Office Action). It is stated in the Office Action that "Nothing in Partain, applicant's arguments, or the

knowledge of the person having ordinary skill in the art would indicate that a change in the charge of the polymer would render the composition unsuitable for delivery of acridine dyes to a wound." (*See* bottom of page 7, 05-OCT-2010 Office Action). This is not the basis for establishment of a *prima facie* case for obviousness. No factual basis or reasoning is provided in the Office Action as to why the skilled artisan would consider the chitosan taught by Partain to be equivalent to the ORC of the present claims or of the cited U.S. Patent No. 7,833,790. U.S. Patent No. 7,833,790 does not even mention or reference chitosan. Partain does not teach or suggest the use of ORC. Applicants respectfully submit that a *prima facie* case for obviousness has not been established, and therefore, that the rejection does not apply. Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this request for review.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5033) for any other required fees, deficiencies or overpayments in connection with this request for review.

Respectfully submitted,

BREDA MARY CULLEN ET AL.

Date: October 20, 2011

By: /Thomas M Sossong Jr/

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